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Doc. No. G867

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Thienna Ho

Filed: Herewith

For: Skin Lightening Composition

NONPUBLICATION REQUEST
UNDER 35 U.S.C. 122(b)(2)(B)(i)

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Sir:

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under U.S.C. 122(b).

4/2/04
Date

Thienna Ho
Thienna Ho

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

TITLE: Skin Lightening Composition

INVENTOR: Thienna I. Ho

DOC NO.: G867

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention generally relates to a composition of matter, and in particular relates to a skin lightening composition for lightening the natural skin color of a user, and also for treating disorders of hyperpigmentation.

2. Description of the Related Art

Skin lighteners are used by millions of individuals for lightening their natural skin color for cosmetic reasons. Skin lighteners are also useful for treating the excessively dark skin color caused by a dermatological condition known as hyperpigmentation, characterized by abnormally increased

pigmentation. A number of compounds are known to lighten skin tone when applied topically. The most popular of these is hydroquinone, which is safe, effective, and available without a prescription. Despite its overall safety and effectiveness, hydroquinone has been known to cause dermatological ochronosis, a progressive discoloration and degeneration of the skin, when used over an extended period of time.

Alternative compounds for lightening skin color are available. However, most of the synthetic or herbal compounds discovered have side effects and are not as effective as hydroquinone. Accordingly, there is a need for a skin lightening composition comprising methyl sulfonyl methane, a nontoxic, natural metabolite which is effective for lightening the natural skin color of a user and for treating disorders of hyperpigmentation, and which has no side effects.

A variety of formulations have been devised for lightening skin, some which do not utilize hydroquinone. For example, United States Patent No. 6,497,860 to Kawato appears to show a skin lightening composition comprising a reducing agent and a cosmetically acceptable carrier for the reducing agent, and which is substantially free of hydroquinone.

A variety of formulations have been devised which contain methyl sulfonyl methane. By way of example, United States Patent No. 6,328,987 to Marini appears to show a skin care composition for improving the appearance of aged or

damaged skin, containing alpha interferon and optionally containing methyl sulfonyl methane. Additionally, United States Patent No. 4,296,130 to Herschler appears to show a method for softening skin and strengthening nails, comprising topically applying methyl sulfonyl methane to the skin and nails. Furthermore, United States Patent No. 6,573,299 to Petrus appears to show a method for the prevention and treatment of the aging eye by the application of a topical composition which optionally comprises methyl sulfonyl methane. Also, United States Patent No. 4,477,469 to Herschler appears to show a preparation containing methyl sulfonyl methane that is applied topically, for softening skin and strengthening nails.

While these formulations and methods of using formulations may be suitable for the particular purpose employed, or for general use, they would not be as suitable for the purposes of the present invention as disclosed hereafter.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a skin lightening composition which is effective in lightening the natural skin color of a user and for treating disorders of hyperpigmentation, and which is safe when topically applied to human skin. Accordingly, the active ingredient of the skin lightening composition is methyl sulfonyl methane, which is highly effective in lightening the natural skin color of a user and for treating disorders of hyperpigmentation, and which is safe when topically applied to human skin.

It is another object of the invention to provide a skin lightening composition that is also safe and effective when orally ingested. Accordingly, methyl sulfonyl methane is a natural metabolite found in the human body, is nontoxic, and is suitable for long-term use by oral ingestion.

It is yet another object of this invention to provide a skin lightening composition suitable for use with a wide variety of different cosmetic "carriers", for ease of application to a user's skin. Accordingly, topical preparations of the skin lightening composition may be dissolved in a liquid solution, or in a carrier such as a cream, a lotion, or a gel. (Orally ingestible preparations may be in liquid, tablet, capsule, or powder form).

The invention is a skin lightening composition for lightening the natural skin color of a user, and for treating disorders of hyperpigmentation. The active ingredient is methyl sulfonyl methane (MSM), a naturally occurring sulfur

compound which may be safely administered topically or orally and which is highly effective for decreasing the ratio of dark melanin to light melanin, and thereby lightening the skin color of a user. The skin lightening composition additionally comprises a liquid solution or a cosmetic carrier such as a cream, a lotion, or a gel, for ease of topical application. Additionally, the skin lightening composition is provided in liquid or solid form for oral ingestion. Topical preparations of the skin lightening composition contain MSM in an amount equal to approximately 1 to 20 weight percent MSM relative to the weight of the entire composition. Orally ingestible preparations of the skin lightening composition contain approximately 200 mg to 5000 mg MSM per serving.

To the accomplishment of the above and related objects the invention may be embodied in the form described in the following description. Attention is called to the fact, however, that the examples given are illustrative only. Variations are contemplated as being part of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The skin lightening composition according to the present invention is safe and effective for lightening the natural skin color of a user, and also for treating disorders of hyperpigmentation, which are characterized by abnormally increased pigmentation. The active ingredient of the skin lightening composition is methyl sulfonyl methane (MSM), a naturally occurring sulfur compound found in the tissues and body fluids of higher mammals, and in fresh fruits and vegetables, meat, milk, seafood, and grains. Sulfur helps the body maintain the three dimensional conformation of proteins required for their proper activity. Sulfur is required for cell regeneration and collagen production in connective tissues of the skin, and in muscles, cartilage, organs and bone. MSM affects the synthesis of the melanin pigments, as will be described.

Melanin is the pigment that largely determines skin color, and is synthesized by the melanocytes in the basal layer of the epidermis. There are two melanin pigments, eumelanin and pheomelanin. Eumelanin is black and pheomelanin is yellow. The ratio of these two pigments in the skin determines how dark or light the skin will be. The synthesis of eumelanin and pheomelanin requires the amino acid tyrosine and the enzyme tyrosinase. Tyrosinase catalyzes the conversion of tyrosine into biochemical intermediates dopa and dopaquinone. Dopaquinone is the

precursor of both eumelanin and pheomelanin in the process of melanogenesis, the biochemical processes which synthesize the melanins. Differences in the ratio of melanin pigments create wide variations in human skin color, ranging from "white" skin color to "black" skin color. Darker skinned individuals have a higher eumelanin to pheomelanin ratio. To lighten skin color, the skin lightening composition targets melanogenesis. In particular, MSM causes dopaquinone to be diverted towards the production of pheomelanin, rather than eumelanin, by safely and effectively increasing intracellular sulfur levels. Under a high intracellular sulfur concentration, melanogenesis automatically leads to an increased synthesis of sulfhydryl-dopa conjugates resulting in the synthesis of the lighter colored pheomelanin instead of the darker colored eumelanin, which is the basis of the activity of MSM in the skin lightening composition.

MSM has been previously used in supplements for treating acne, arthritis, muscle pain, and skin damage and aging. MSM can be used safely and effectively for lightening the natural skin color of a user and for treating disorders of hyperpigmentation. Methyl sulfonyl methane is all natural, nontoxic, non-allergenic, and non-pyretic, and is safe and effective when administered topically or when orally ingested, even over prolonged periods of time. Moreover, MSM has no undesirable pharmacological effects when taken in conjunction with other substances.

The skin lightening composition is provided in two types of preparations. In particular, the skin lightening composition is provided in topical preparations which are applied directly to the skin, and also in orally ingestible preparations. Topical preparations of the skin lightening composition comprise MSM dissolved or mixed within a vehicle. The vehicle may be a liquid solution, or it may be a cosmetic carrier such as a cream, a lotion, or a gel. Topical preparations of the skin lightening composition contain MSM at an amount equal to approximately 1 to 20 weight percent MSM relative to the weight of the entire skin lightening composition. Liquid solutions for topical application may include MSM in aqueous or non-aqueous solutions or emulsions. It is contemplated that the skin lightening composition may be combined with other cosmetics, such as moisturizers or perfumes, in order to provide a skin lightening composition with properties in addition to its skin lightening properties. By way of example, the skin whitening formula may comprises a moisturizing face and body cream into which the MSM has been blended. It is additionally contemplated that the skin lightening composition will be provided as a solid mixture, e.g. a mixture of MSM with vitamins and minerals that a user can mix with water and use for washing the face and body. Alternately, the skin whitening formula may be supplied as a liquid solution which may be directly used as a face and body wash.

Orally ingestible preparations of the skin lightening composition are provided in liquid or in solid form, and contain approximately 200 mg to 5000 mg MSM per serving. Orally ingestible preparations of the skin whitening formula may be in an edible form such as a tablet, a pill, a capsule, or in powder form. MSM can also be orally ingested in a nutritious mixture that contains vitamins, minerals, herbs, antioxidants, proteins, and/or amino acids.

In conclusion, herein is presented a skin lightening composition for lightening the natural skin color of a user, and also for treating disorders of hyperpigmentation. The invention is illustrated by example throughout the written description. It should be understood that numerous variations are possible, while adhering to the inventive concept. Such variations are contemplated as being a part of the present invention.

CLAIMS

What is claimed is:

1. A topical preparation of a skin lightening composition, suitable for direct application to the face and body of a user, for lightening the natural skin color of the user and for treating disorders of hyperpigmentation, comprising:

methyl sulfonyl methane, a naturally occurring sulfur compound which lightens the skin; and

a vehicle; and

wherein the methyl sulfonyl methane is dissolved within the vehicle at an amount equal to approximately 1 to 20 weight percent methyl sulfonyl methane relative to the weight of the entire skin lightening composition.

2. The topical preparation of a skin lightening composition as recited in claim 1, wherein the vehicle is a liquid solution.

3. The topical preparation of a skin lightening composition as recited in claim 2, further comprising a perfume.

4. The topical preparation of a skin lightening composition as recited in claim 3, further comprising a nutrient chosen

from a class of nutrients consisting of vitamins and minerals.

5. The topical preparation of a skin lightening composition as recited in claim 1, wherein the vehicle is a cosmetic carrier chosen from a class of cosmetic carriers consisting of creams, lotions, and gels, wherein the methyl sulfonyl methane is blended within said cosmetic carrier at an amount equal to approximately 1 to 20 weight percent methyl sulfonyl methane relative to the weight of the entire skin lightening composition.

6. The topical preparation of a skin lightening composition as recited in claim 5, further comprising a perfume.

7. The topical preparation of a skin lightening composition as recited in claim 6, further comprising a nutrient chosen from a class of nutrients consisting of vitamins and minerals.

8. An orally ingestible preparation of a skin lightening composition, comprising:

approximately 200 mg to 5000 mg methyl sulfonyl methane per serving; and

an edible form chosen from a class of edible forms consisting of tablets, pills, capsules, and powders; and

wherein the methyl sulfonyl methane is contained within the edible form.

9. The orally ingestible preparation of a skin whitening formula as recited in claim 8, further comprising at least one nutrient chosen from a class of nutrients consisting of vitamins, minerals, antioxidants, proteins, and amino acids, and wherein said at least one nutrient is contained within the edible form.

10. A method for lightening the natural skin color of a user and for treating disorders of hyperpigmentation, utilizing a topical preparation of a skin lightening composition comprising methyl sulfonyl methane and a vehicle, wherein the methyl sulfonyl methane is dissolved within the vehicle at an amount equal to approximately 1 to 20 weight percent methyl sulfonyl methane relative to the weight of the entire skin lightening composition, said method comprising the step of directly applying the skin lightening composition to the face and body of a user, and thereby lightening the skin of the face and the body.

ABSTRACT

A skin lightening composition for lightening the natural skin color of a user, and for treating disorders of hyperpigmentation. The active ingredient is methyl sulfonyl methane (MSM), a naturally occurring sulfur compound which may be safely administered topically or orally and which is highly effective for decreasing the ratio of dark melanin to light melanin, and thereby lightening the skin color of a user. The skin lightening composition additionally comprises a liquid solution or a cosmetic carrier such as a cream, a lotion, or a gel, for ease of topical application. Additionally, the skin lightening composition is provided in liquid or solid form for oral ingestion. Topical preparations of the skin lightening composition contain MSM in an amount equal to approximately 1 to 20 weight percent MSM relative to the weight of the entire composition. Orally ingestible preparations of the skin lightening composition contain approximately 200 mg to 5000 mg MSM per serving.

FILE NO.: G867

DECLARATION AND POWER OF ATTORNEY
Original Application

As the below named inventor I declare that the information given herein is true, that I believe that I am the original, first and sole inventor of the invention entitled:

Skin Lightening Composition

which is described and claimed in the attached specification;
that I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to this application, or in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inven tor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application, that I acknowledge my duty to disclose information of which I am aware which is material to the patentability of this application in accordance with 37 CFR §1.56, and that no application for patent or inventor's certificate on this invention has been filed by me or my legal representatives or assigns in any country foreign to the United States of America except as identified below. I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

POWER OF ATTORNEY:

As named inventors, we hereby appoint the following agent to prosecute this application, and transact all matters before the United States Patent and Trademark Office: Customer Number 000039747, (2071 Clove Road, Staten Island, NY 10304)

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 1: Thierry Ho DATED: 4/2/2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application for Patent of: Thienna Ho
Docket No. G867

Serial or Patent No.: Filed or Issued: Herewith

For: :Skin Lightening Composition

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office with regard to the invention entitled as described in:

[x] the specification filed herewith.
[ ] application serial no. filed
[ ] patent no. issued

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[x] no such person, concern, or organization
[ ] persons, concerns or organizations listed below*

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of inventor 1: Thienna Ho

Thienna Ho

Signature of Inventor

Date: 4/2/04